

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

SUCAMPO AG, SUCAMPO
PHARMACEUTICALS, INC.,
SUCAMPO PHARMA, LLC, TAKEDA
PHARMACEUTICAL COMPANY
LIMITED, TAKEDA
PHARMACEUTICALS USA, INC., and
TAKEDA PHARMACEUTICALS
AMERICA, INC.,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS LLC,

Defendant.

Civil Action No. 17-2577 (PGS) (LHG)

(Filed Electronically)

CONSENT JUDGMENT AND ORDER OF PERMANENT INJUNCTION

This action for patent infringement (the “Patent Litigation”) has been brought by Plaintiffs Sucampo AG, Sucampo Pharmaceuticals, Inc., Sucampo Pharma, LLC (collectively, (“Sucampo”), Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals USA, Inc., and Takeda Pharmaceuticals America, Inc. (collectively, “Takeda” and, together with Sucampo, “Plaintiffs”) against Defendant Amneal Pharmaceutical LLC (“Amneal”) for infringement of United States Patent Nos. 6,982,283 (“the ’283 Patent”), 8,026,393 (“the ’393 Patent”), 8,097,653 (“the ’653 Patent”), 8,338,639 (“the ’639 Patent”), and 8,389,542 (“the ’542 Patent”) (collectively, the “Sucampo Patents”). Plaintiffs’ commencement of the Patent Litigation was based on its receipt of notice from Amneal that Amneal filed ANDA No. 209450 with the United States Food and Drug Administration containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) directed to the Sucampo Patents and seeking approval to market generic versions of 8 mcg and 24 mcg lubiprostone capsules.

Plaintiffs and Amneal have now agreed to a good-faith final resolution regarding this Patent Litigation on the expectation and belief that this would eliminate the substantial litigation costs that would otherwise be incurred by both Plaintiffs and Amneal during the Patent Litigation, while also serving the public interest by saving judicial resources and avoiding the risks to each of the parties associated with infringement. This Court shall retain jurisdiction over Plaintiffs and Amneal to enforce the final settlement.¹ Plaintiffs and Amneal also believe that this resolution gives them the procompetitive opportunity to more productively use money and other resources that would have been spent in the continued prosecution and defense of this

¹ The parties agree to provide the Court, under seal, with a copy of their settlement agreement upon request.

Patent Litigation, to the benefit of the parties and consumers alike, such as by investing more money in pharmaceutical research and development.

Each of Plaintiffs and Amneal acknowledge there is significant risk to each of them associated with the continued prosecution of this Patent Litigation and have consented to judgment through a final resolution as reflected in the Consent Judgment set forth herein. The Court, upon the consent and request of Plaintiffs and Amneal, hereby acknowledges the following Consent Judgment and, upon due consideration, issues the following Order.

Plaintiffs and Amneal now consent to this Consent Judgment and Order of Permanent Injunction and

IT IS, this 19 day of September, 2018,

HEREBY ORDERED, ADJUDGED AND DECREED that:

1. This Court has subject matter jurisdiction over this patent infringement action, and personal jurisdiction over Plaintiffs and Amneal for purposes of this action. Venue is proper in this Court as to Plaintiffs and Amneal as to this action.

2. In this Patent Litigation, which was filed on April 13, 2017, Plaintiffs have charged Amneal with infringement of the Sucampo Patents in connection with Amneal's submission of Abbreviated New Drug Application ("ANDA") No. 209450 directed to generic tablets containing 8 mcg and 24 mcg of lubiprostone per capsule ("Amneal's ANDA No. 209450 Products") to the U.S. Food and Drug Administration ("FDA").

3. In response to Plaintiffs' charges of patent infringement, Amneal has alleged certain defenses, including that the Sucampo Patents are invalid. No decision has been obtained by the parties from this Court regarding these charges of infringement or these defenses.

4. Amneal has not obtained a decision from the Court finding that it has rebutted the statutory presumption that the Sucampo Patents are valid and enforceable in the Patent Litigation.

5. Amneal admits that the submission of ANDA No. 209450 containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use and/or sale of Amneal's ANDA No. 209450 Products within the United States before the expiration of the Sucampo Patents was a technical act of infringement of the Sucampo Patents under 35 U.S.C. § 271(e)(2)(A). This admission is further without prejudice to any claim, defense or counterclaim in any future action between Amneal and Plaintiffs, or any successor-in-interest to Sucampo, regarding the Sucampo Patents and/or a generic lubiprostone product other than Amneal's ANDA No. 209450 Products.

6. Both parties have agreed that each of the defenses and counterclaims set forth in Amneal's Answer, including the allegations and averments contained therein, should be dismissed, without prejudice.

7. Amneal, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, any generic capsule product containing 8 mcg and/or 24 mcg of lubiprostone per capsule that is the subject of ANDA No. 209450 until January 1, 2023 or at such earlier date as may be permitted by the resolution to which the Parties have agreed.

8. Plaintiffs and Amneal each expressly waive any right to appeal or otherwise move for relief from this final Consent Judgment and Order of Permanent Injunction.

9. This Court retains jurisdiction over Plaintiffs and Amneal for purposes of enforcing this final Consent Judgment and Order of Permanent Injunction.

10. This Consent Judgment and Order of Permanent Injunction is without prejudice to, and shall have no preclusive effect as to, any claim, defense or counterclaim in any future action between Amneal or any successor-in-interest to Amneal, and Plaintiffs, or any successor-in-interest to Plaintiffs, regarding the Sucampo Patents and/or a generic lubiprostone product other than Amneal's ANDA No. 209450 Products.

11. The Clerk of the Court is directed to enter this final Consent Judgment and Order of Permanent Injunction forthwith, and thereafter close this matter.

IT IS HEREBY STIPULATED:

Dated: August 17, 2018

By: s/ William C. Baton
Charles M. Lizza
William C. Baton
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102
(973) 286-6700
clizza@saul.com
wbaton@saul.com

*Attorneys for Plaintiffs
Sucampo AG, Sucampo Pharmaceuticals,
Inc., Sucampo Pharma, LLC, Takeda
Pharmaceutical Company Limited, Takeda
Pharmaceuticals USA, Inc., and Takeda
Pharmaceuticals America, Inc.*

Of Counsel:

Preston K. Ratliff II
Joseph M. O'Malley, Jr.
Evan Diamond
Yousef M. Mian
PAUL HASTINGS LLP
200 Park Avenue
New York, NY 10166

Dated: August 17, 2018

By: s/ Rebekah R. Conroy
Rebekah R. Conroy
STONE CONROY LLC
25A Hanover Road, Suite 301
Florham Park, NJ 07932
Telephone: (973) 400-4181
Facsimile: (973) 498-0070
rconroy@stoneconroy.com

Of Counsel:

Paul S. Tully, Ph.D.
Kevin E. Noonan, Ph.D.
Sydney R. Kokjohn
Andrea K. Orth
MCDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 South Wacker Drive
Chicago, Illinois 60606
(312) 913-0001

*Attorneys for Defendant
Amneal Pharmaceuticals LLC*

(212) 318-6000

*Attorneys for Plaintiffs
Sucampo AG, Sucampo
Pharmaceuticals, Inc., and Sucampo
Pharma, LLC*

William F. Cavanaugh
Laura B. Kaufman
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036
(212) 336-2000

*Attorneys for Plaintiffs
Takeda Pharmaceutical Company Limited,
Takeda Pharmaceuticals USA, Inc., and
Takeda Pharmaceuticals America, Inc.*

SO ORDERED:

This 19 day of sept, 2018.



THE HONORABLE PETER G. SHERIDAN
United States District Judge